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Paracetamol Versus Fentanyl for Pain Control in Patients Under Extracorporeal Shockwave Lithotripsy

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Abstract

Background: Extracorporeal Shockwave Lithotripsy (ESWL) is a safe and noninvasive management for upper urinary tract calculi. It is potentially a painful procedure. There are different analgesic agents for pain relief during ESWL. Successful treatment depends on good management of pain. Therefore, a standard protocol is needed for administering an analgesic agent. This study was designed to compare the efficacy and side effects of paracetamol and fentanyl for pain control during extracorporeal shock wave lithotripsy.
Methods: In this randomized clinical trial, 102 patients with upper urinary tract stones undergoing SWL were randomly divided to two groups. Group P received 15 mg/kg of paracetamol 10 minutes before the procedure, and group F received 1 μg/kg intravenous fentanyl three minutes before the procedure. Pain scores were assessed with the 10-score linear Visual Analogue pain Scale (VAS). The VAS scores, systolic and diastolic blood pressure, and peripheral oxygen saturation were recorded before the procedure and every 10 minutes during the ESWL. Side effects (nausea and vomiting) and satisfaction scores were recorded.
Results: There were no statistically significant differences in VAS scores between the two groups, except for those at 30 minutes, at which group P showed a higher VAS value. There were less supplemental analgesia requirement and side effects in the P group compared with fentanyl.
Conclusions: This study showed that paracetamol could be an effective and safe alternative analgesic for pain control during ESWL.

Keywords: ESWL, Fentanyl, Paracetamol

1. Background

Urolithiasis is considered as the third most common urological disease. Increased changes in the worldwide incidence and prevalence of nephrolithiasis have been reported (1, 2). Extracorporeal shock wave lithotripsy was introduced for the first time in 1980 and it revolutionized urolithiasis treatment and replaced open stone surgery (3, 4). It is a useful, safe, and noninvasive management of urinary stones. Despite the introduction of modern lithotriptors, pain is common among patients undergoing the ESWL procedure. Good pain management after surgery is important for optimal stone fragmentation. The ESWL procedure can be carried out on an outpatient basis. Most patients need appropriate analgesia with minimal adverse effects. There are different analgesic agents for pain relief during ESWL, including opioid, NSAIDS, and local anesthetic agents. Successful treatment depends on good management of pain. Therefore, a standard protocol is needed for administering the analgesic agent (3, 5, 6). The aim of this randomized single blinded study was to compare the efficacy and side effects of paracetamol and fentanyl for pain control during extracorporeal shock wave lithotripsy.

2. Methods

In this randomized single-blind clinical trial, 102 patients (74 males and 28 females) undergoing shock wave lithotripsy at a referral nephrology center in 2015 and 2016 were enrolled. This study was registered at the Iranian registry of clinical trial (IRCT) and allocated a unique code (Identifier IRCT2016072329034N1). After the clinical trial study was approved by the local ethical committee and written informed consents were obtained, the patients were randomly assigned to receive either 1 μg/kg intravenous fentanyl three minutes before ESWL (group F) or 15 mg/kg intravenous paracetamol ten minutes before ESWL. A third-generation lithotripter (Dornier HM-3) was used for ESWL lithotripter.

Inclusion criteria were age of 20 to 65 years, being scheduled for elective ESWL with American society of anes-

thesiologists (ASA) physical status I or II, and having upper ureteral stones of 6 to 20 mm. Exclusion criteria were history of chronic use of analgesics or alcohol, use of any analgesic drug within three days before the procedure, allergy study drugs, treatment with sedative or antidepressant drugs, signs and symptoms of urinary tract infection, allergy to study drugs, moderate to severe hydroureteronephrosis, presence of multiple and/or bladder and/or radiolucent stones, pregnancy, and sensory neurological disease.

The visual analogue scale (VAS) with 10-score linear visual analogue pain scale ranging from zero (no pain) to ten (greatest pain), during SWL, was compared between the groups. When VAS value was greater than three, supplemental analgesia was administered to both groups. Twenty-five micrograms of intravenous fentanyl was given in this condition. Electrocardiogram (ECG) and pulse oximeters were used to monitor patient's need for oxygen therapy. While the saturation was less than 86%, face masks were used for supplementary oxygen. Side effects ranged from one to three; one was related to no nausea, two related to nausea without vomiting and nausea with vomiting was shown with a score of three. Age, gender, weight, stone size, ASA physical status, and side effects were recorded.

All statistical analyses were conducted with SPSS, version19. Quantitative data was expressed as mean ± standard deviation and qualitative data was also demonstrated as frequencies and percentages. Statistical analysis was done using chi-square, Kolmogorov-Smirnov, and Mann-Whitney-U tests. P values of less than 0.05 were regarded statistically significant.

3. Results

The mean age of patients was 43.4 ± 13.2 years. 34 patients were males and 28 were females. The mean weight of patients was 78.8 ± 11.8 kilograms and the mean stone size was 11.08 ± 4.1 millimeters. There was no significant difference in gender, ASA physical status, age, and systolic and diastolic arterial pressure between the groups (Tables 1 and 2).

Supplemental analgesia requirement was significantly lower in the P group compared with the F group and also the P group had fewer side effects than the F group (Table 3). There was higher peripheral O_2 saturation in the P group (Table 4).

Table 1. Demographic Data of Both Groups[a]

Variables	Group P	Group F	P-Value
Age (yr)	41.9 ± 13.02	44.8 ± 13.4	0.271
Gender (male/female)	41/10	33/18	0.076
ASA physical status (I/II)	42/9	40/11	0.681
Weight	77.2 ± 11.4	80.47 ± 12.2	0.183
Stone size	10.5 ± 3.8	11.6 ± 4.3	0.143

Abbreviations: ASA; American society of anesthesiologists, P group; Paracetamol group, F group; Fentanyl group.
[a] Values are represented as mean ± SD and ratio for sex and ASA status.

4. Discussion

Effective analgesia during ESWL is essential for good outcomes. Various opioid agents (morphine, pethidine, and fentanyl) are well known for the management of pain during SWL yet their main adverse effects, such as decrease in oxygen saturation, nausea, vomiting, drowsiness, and hypersensitivity, have led to their replacement with analgesia. Paracetamol is a relatively safe and effective analgesic. It is the most commonly used analgesic worldwide for other indications. In cases of severe pain, it can reduce the consumption of opioids (3, 6, 7).

Although opioids are commonly used drugs for pain control during ESWL, other analgesics with less adverse effects can be effective alternatives in pain control. Paracetamol has recently been considered for its safety compared with other analgesia (3). The present study characterized the comparative effects of paracetamol and fentanyl on pain relief during extracorporeal shock wave.

Akcali et al. studied 90 patients and concluded that one gram of paracetamol is significantly effective in comparison with lornoxicam and tramadol. The mean VAS scores were similar among these three groups at all measured times during SWL, except for those at five and twenty minutes, at which the paracetamol group showed better pain control. They also found paracetamol as an effective and safe agent in pain control during SWL as reported by the current study. There was no significant difference between the three groups regarding supplemental drug consumption (8). In concomitance with this study, Eker et al. demonstrated that IV paracetamol reduces propofol-ketamine consumption during ESWL procedures in pediatric patients (9).

The current study showed that paracetamol could be used for pain control during ESWL. There were no significant statistical differences in VAS scores between the two groups except for those at 30 minutes, at which group P showed a higher VAS value. However, there was less supplemental analgesia requirement in the paracetamol group. Based on the current results, paracetamol is an effective analgesic with significantly fewer side effects in comparison with fentanyl and there was higher peripheral O_2 satu-

Table 2. Diastolic and Systolic Arterial Pressure Data of Both Groups[a]

	Diastolic Blood Pressure			Systolic Blood Pressure		
	Group P	Group F	P-Value	Group P	Group F	P-Value
Baseline	75.8 ± 7.8	79.5 ± 10.6	0.005	122.5 ± 11.1	130.1 ± 10.9	0.0001
10 min	76.4 ± 8.2	79 ± 9.9	0.12	123 ± 10.2	124.8 ± 18.7	0.05
20 min	77.7 ± 8	78 ± 8.7	0.55	123.1 ± 10.2	126.4 ± 10.3	0.11
30 min	77.4 ± 8.4	75.2 ± 9.1	0.15	124 ± 10.5	124.7 ± 8.5	0.57
After ESWL	77.1 ± 6.3	75.2 ± 8.8	0.73	119.1 ± 7.8	121.9 ± 8.0	0.02

Abbreviations: F group; Fentanyl group, P group; Paracetamol group.
[a] Values are represented as mean ± SD.

Table 3. Supplement Drug User and Side Effects after the ESWL Procedure[a]

	Group P	Group F	P-Value
Supplement drug user	14 (27.5)	32 (62.7)	0.001
Nausea without vomiting	2 (3.9)	14 (27.5)	0.0001
Nausea with vomiting	0 (0)	3 (5.8)	

Abbreviations: F group; Fentanyl group, P group; Paracetamol group.
[a] Values are represented as No. (%)

Table 4. Peripheral Saturation O_2 Data of Both Groups[a]

	Group P	Group F	P-Value
Baseline	90.6 ± 1.2	90.0 ± 1.8	0.0001
10 min	91.6 ± 1.2	90.9 ± 1.7	0.0001
20 min	91.3 ± 1.1	89.7 ± 1.3	0.0001
30 min	90.6 ± 1.3	89.4 ± 1.3	0.0001
After ESWL	92.9 ± 1.6	91.9 ± 1.2	0.0001

Abbreviations: A group; Acetaminophen group, F group; Fentanyl group.
[a] Values are represented as mean ± SD.

Table 5. Comparisons of Mean Visual Analog Scale Scores in the Two Groups

	Group P	Group F	P-Value
Baseline	1.90 ± 1.5	2.64 ± 2.5	0.35
10 min	2.64 ± 1.6	2.62 ± 1.9	0.50
20 min	3.37 ± 1.6	3.00 ± 1.9	0.17
30 min	3.47 ± 1.8	2.49 ± 1.7	0.0001
At the end of ESWL	1.57 ± 0.7	1.70 ± 1.2	0.8

Abbreviations: F group; Fentanyl group, P group; Paracetamol group, VAS; visual analog scale.

ration in the P group.

In contrast, Ozkan et al. evaluated the comparison of pain relief effect of paracetamol, lornoxicam, and tramadol as additional administration analgesics on patients during shockwave lithotripsy. Patients were divided to three groups and all of them were given tramadol. The mean VAS scores were lower in the group, which received lornoxicam in comparison with paracetamol and only tramadol (10). In concomitance with this research, Yesil et al. conducted a study on efficacy of diclofenac, dexketoprofen, and hyoscine plus paracetamol. Patients received analgesics half an hour before the ESWL procedure. It has been reported that diclofenac sodium is more effective compared with other groups and mixture of hyoscine plus paracetamol reduces the VAS scores. Therefore, if hyoscine plus paracetamol had been given an hour before operation, it might have been better than dexketoprofen and diclofenac (11).

Andreou et al. evaluated the effects of piroxicam analgesia and tramadol analgesia on pain control during electromagnetic extracorporeal lithotripsy. They conducted a randomized, double blind, clinical trial on 170 patients, divided to two groups. Pain and discomfort score was measured by VAS. This study reported that both piroxicam and tramadol are suitable for the treatment of pain during outpatient extracorporeal lithotripsy. However, tramadol had more side effects (12).

Overall, according to the current results, it may be concluded that paracetamol can be an effective and safe alternative analgesic for pain control during ESWL and use of this analgesic is recommended. However, further studies with larger sample size and multi-center sampling is required to attain more definite results.

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